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Unveiling process knowledge for plasmid DNA fermentation across upstream scales

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UNVEILING PROCESS KNOWLEDGE FOR PLASMID DNA FERMENTATION ACROSS UPSTREAM SCALES

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Plasmids DNA (pDNA) are small, circular pieces of DNA used to deliver genetic information and are key inputs in gene therapies, cell therapies, gene editing, and in particular mRNA vaccines and therapies. There are currently ~1,400 therapeutic assets in development across these modalities, with the pipeline expected to grow rapidly in the next years given the pandemic scenario. Developing biopharmaceuticals derived from microbial fermentation such as pDNA relies upon performant bioreactors to allow a rapid scale up to commercial batches. For this it is relevant to minimize any possible risks while developing a process that adheres to industry quality standards. The choice of a well characterized system plays an important role from R&D through to production stages in accelerating development timelines and ensuring process success. The aim of this poster is to provide evidence to demonstrate the advantages of a microbial process developed using Sartorius scalable microbial solutions, DoE software and analytical methods for pDNA production. The method chosen to showcase this consistency is based on the DECHEMA Guidelines for Engineering Characterization principles which include a set of standard conditions for bioreactor characterization described further in the poster. The data showcased will be on real case studies, applicable for pDNA fermentation.

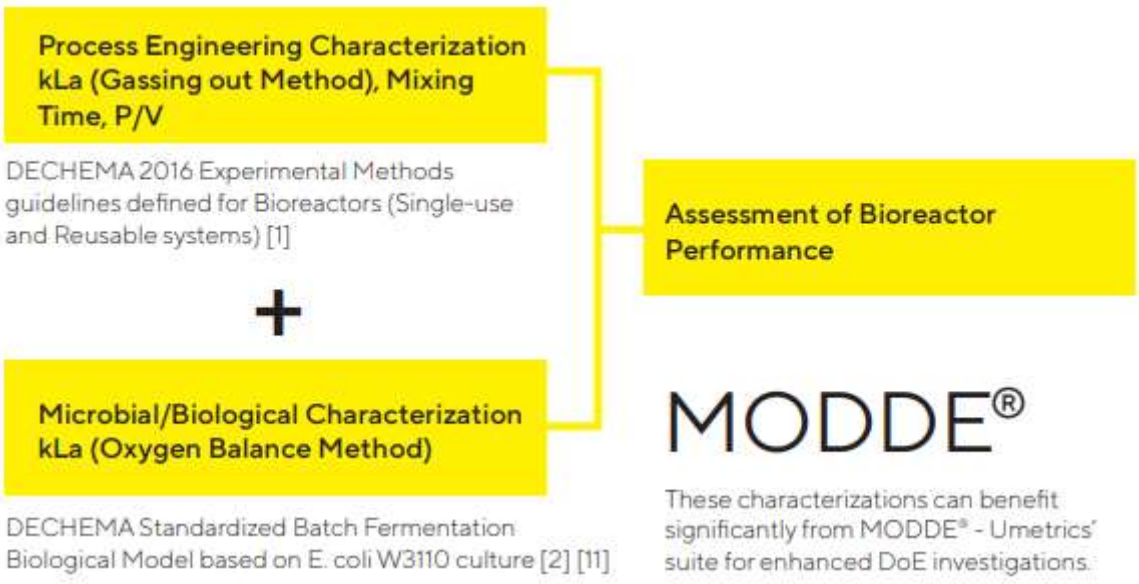

Figure 1 – DECHEMA Characterization Principles